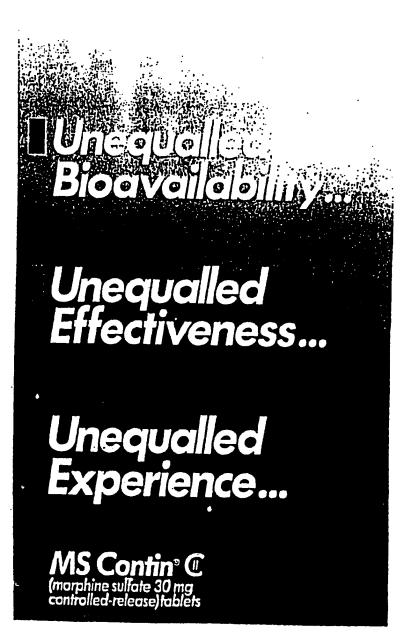


MS Contin is Unequalled...







P 041765

6/19/02

Filed 09/21/2007

Unequalled Bioavailability...

■ MS Contin has superior 12-hour bioavailability: MS Contin is 27% more bioavailable than Roxanol SR.

Bioavailability:

"The extent to which a drug reaches its site of action or a biological fluid from which the drug has access to its site of action."

Bioavailability (0-12 hr) of MS Contin 30 mg Tablets vs. Roxanol SR 30 mg Tablets as determined by plasma drug levels in a crossover study in 18 normal volunteerst

MS Contin Tablets

AUC (0-12 hr; $ng/ml \times hr$)

150

Important Note: While there is an indirect relationship between plasma morphine levels and analgesia, higher plasma levels are generally associated with superior relief of pour, as demonstrated in the literature. There is a kig time or hysteresis. weens the turns of peak phruns morphine levels and the time of peak drug effects."

12-Hour MS Contin ...

MS Contin (morphine sulfate 30 mg controlled-release) tablets

- No other morphine product is bioequivalent to MS Contin.
- MS Contin and Roxanol SR are not bioequivalent, therefore, Roxanol SR is not therapeutically interchangeable with MS Contin.
- MS Contin reaches a significantly higher peak concentration, for more effective analgesia.

Bioequivalence:

'They [pharmaceutical formulations] are said to be biologically equivalent if they yield similar concentrations of drug in blood and tissues...Pharmaceutical preparations that are chemically equivalent but not biologically or therapeutically equivalent are said to differ in their bioavailability."

The three criteria for bioequivalency are comparable	Results of Comparative Study MS Contin Rozanol SR (2 × 30 mg) (2 × 30 mg)
 bioavailability (calculated from area under the time-concentration-curve) 	AUC 147 116
2. time to peak plasma concentration	T _{max} 2.7 2.2 (hrs)
3. peak concentration	Cmox 29 17 (ng/ml)
Time to Peak Concentration (Tmax)*	Peak Concentration (Cmax)
MS Contin	MS Confin
Roxanol SR	Roxanol SR
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Proven Against Cancer Pain

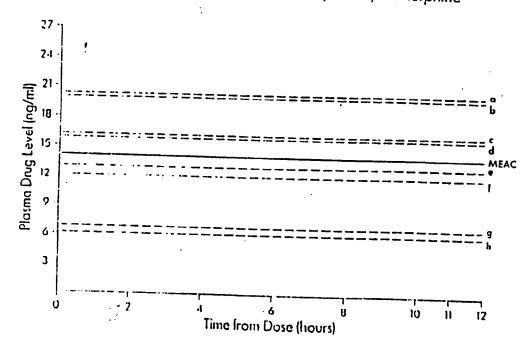
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Unequalled Effectiveness...

What is the effective analgesic level of oral morphine?

A careful review of the literature. Indicates the complexity of defining effective analgesic plasma morphine levels. However, there is generally a "Minimally Effective Analgesic Concentration" (MEAC) of plasma morphine below which no unalgesia is provided (see Chart below).

Minimally Effective Analgesic Concentrations (MEAC) of Morphine



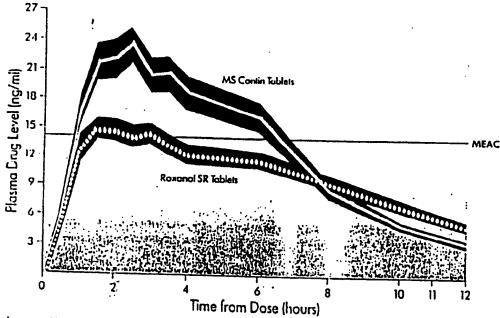
12-Hour MS Contin.

MS Contin (morphine sulfate 30 mg controlled-release) tablets

Document 22-12

- MS Contin achieves <u>significantly higher</u> analgesic concentrations!
- MS Contin maintains plasma levels above the minimally effective analgesic concentration (MEAC) significantly longer.

Plasma morphine concentration (mean \pm SE) following equal doses of MS Contin and Roxanol SRt



hain those as older subjects and as palients s with undvariced disease. For example, the appa cted to be prolonged in such patients.

ally, there is a lag time, or hysteresis, between the time of peak plasma morphise l

Proven Against Cancer Pain

Unequalled Experience...

- Extensive published clinical documentation that supports 12-hour efficacy and safety¹⁻¹⁴
- Over 6 years' proven clinical experience with over a half-million prescriptions'
- MS Contin has a clinically documented safety profile:

In over 95% of patients, side effects were fewer or equal to pre-study analgesic¹⁵⁻¹⁷

Percent of patients experiencing fewer or equal side effects¹⁵⁻¹⁷

Study #1: Memorial Sloan-Kettering Cancer Center

55% of patients experienced fewer side effects 21% of patients experienced equal side effects

Study #2: New York University School of Medicine

94% of patients experienced fewer side effects 6% of patients experienced equal side effects

Study #3: Bowman Gray School of Medicine

52% of patients experienced fewer side effects 48% of patients experienced equal side effects

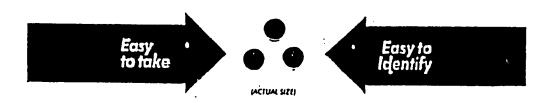
12-Hour MS Contin...

MS Contin* (morphine sulfate 30 mg controlled-release) tablets

- MS Contin is the subject of two international symposia on pain control. 18-19
- Safety and efficacy demonstrated at prestigious cancer treatment centers in over 1200 study patients.
- Professional educational support:

 Speakers' Bureau; Educational Slides and Videotapes, including "Cancer Pain Management" Chaired by Dr. Kathleen M. Foley of Memorial Sloan-Kettering Cancer Center.
- MS Contin Tablets are small, round and film coated.

Their distinctive lavender color makes them easy to recognize and identify. Their small size (less than half that of Roxanol SR) makes them easy to swallow.



International of the Studies of Control of C

Proven Against Cancer Pain

MS Contin[®] is Unequalled...

The <u>only</u> 12-hour oral narcotic analgesic proven against cancer pain.

- Superior 12-hour bioavailability 27% more bioavailable than Roxanol SR.
- No other morphine product is bioequivalent to MS Contin; therefore, none is therapeutically interchangeable.
- Achieves a <u>significantly higher</u> peak concentration for more effective analgesia.
- Maintains plasma morphine levels above the minimally effective analgesic concentration (MEAC) <u>significantly longer</u> for effective pain relief.
- Published clinical documentation of superior or equal efficacy compared to immediate-release morphine and other oral opioid analgesics.
- Proven safety profile published clinical documentation shows fewer side effects than previous analgesic (Hydromorphone, Methadone, Oxycodone, Codeine, Meperidine).

Also available

MSIR - Useful in starting patients on morphine or for treating breakthrough or incident pain.

(morphine sulfate) 15 mg rawl 30 mg (morphi

12-hour MS Contin® @

(morphine sulfate 30 mg controlled-release) tablets

Proven Against Cancer Pain

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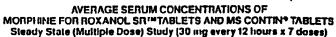
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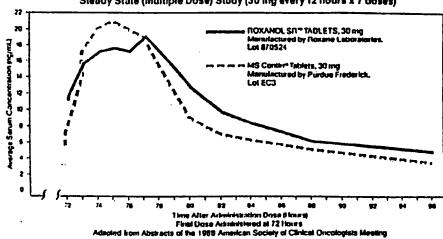
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Multiple-dose randomized crossover trial demonstrates Roxanol SR and MS Contin are bioequivalent.

Li Evaluations of standard pharmacokinetic parameters (AUC 79-96 hr, AUC 72-84 hr, Crnax and Cavg) showed less than 10% difference between the two sustained release morphine treatments.

U The investigators concluded that Roxanol SR is bioequivalent to MS Contin.

More cost-effective than MS Contin

☐Roxanol SR offers greater cost containment benefits for hospitals.*

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Dosing and Administration

The patients should first be stabilized on Roxanol Concentrated Oral Solution. Convert to Roxanol SR by dividing the total daily Roxanol requirement (an milligrams) by three and administering as Roxanol SR fiablets every eight hours. The dose and dosage schedule can be adjusted for greater flexibility according to severity of pain as well as for the patient's underlying disease, age, and size.

Tablets must be swallowed whole,...not broken, crushed, or chawed. Tablets have a methyl cellulose coating for easier swallowing.

